UNITED STATES DISTRICT COURT
SOUTHERN DISTRICT OF NEW YORK

AILEEN GOLDSTEIN, *individually and on behalf of all others similarly situated*, Plaintiff,	22-cv-00088 (LJL)
-v-	OPINION AND ORDER
WALMART, INC., Defendant.	

LEWIS J. LIMAN, United States District Judge:

Aileen Goldstein ("Plaintiff" or "Goldstein") brings this action, individually and on behalf of all others similarly situated, against Walmart, Inc. ("Defendant" or "Walmart"). She alleges, on behalf of a nationwide class, breach of express warranty and breach of the Magnuson-Moss Warranty Act ("MMWA"), and on behalf of a consumer protection subclass, violations of the consumer protection acts of various states[1] and Washington, D.C. Dkt. No. 15. On behalf of a New York subclass, she alleges violations of sections 349 and 350 of New York General Business Law. *Id.* Walmart moves, pursuant to Federal Rules of Civil Procedure 12(b)(1) and 12(b)(6), to dismiss Goldstein's amended complaint ("Complaint") for lack of subject matter jurisdiction and for failure to state a claim for relief. Dkt. No. 22.

For the following reasons, the motion to dismiss is GRANTED.

BACKGROUND

The Court accepts as true the well-pleaded allegations of the Complaint, as supplemented by the documents incorporated by reference, for the purposes of this motion to dismiss.

[1] The state statutes are New York, Massachusetts, Missouri, Rhode Island, Vermont, and Washington. Dkt. No. 15 at 14.

I. The Allegations of the Complaint

Goldstein is a citizen and domiciliary of New York. Dkt. No. 15 ¶ 5. Walmart manufactures, distributes, markets, and sells an over-the-counter ("OTC") cough medicine sold under the brand "Equate," which includes versions of the product similar to brands like Robitussin and DayQuil. *Id.* ¶¶ 1, 10. Like those brands, many of the Equate products contain the active ingredient Dextromethorphan Hydrobromide ("DXM"). Walmart sells products containing DXM which are prominently marked on the label as "non-drowsy." *Id.* ¶¶ 1, 11. Such products ("Non-Drowsy Equate Products") include, for example, Adult Tussin DM Cough Syrup, Adult Daytime Severe Cold & Flu medicine, and Daytime Tussin DM Max. *Id.* ¶ 11.

In or around March 2021, Goldstein bought a bottle of Equate Daytime Tussin DM Max from a Walmart store in Monticello, New York (the "Product"). *Id.* ¶ 32. The package for the Product said "Non-Drowsy" prominently on the label, and she read and relied on that statement when purchasing the Product. *Id.* But after taking the recommended dose of the medication as directed on the label by Walmart, Goldstein became unexpectedly drowsy. *Id.* She was not on any other medication that would have caused drowsiness and there were no other potential causes for drowsiness aside from the ingredients in Defendant's Product. *Id.*

Goldstein claims that, notwithstanding the claim on the label, "products containing DXM—like the Non-Drowsy Equate Products—do cause drowsiness, and drowsiness is a documented side effect of DXM" at recommended dosages. *Id.* ¶¶ 16, 17. The Complaint cites a study allegedly showing that "'[s]omnolence is a common side effect of centrally acting antitussive drugs' like [DXM] and that 10.4% of users of products containing DXM develop drowsiness within three days of starting treatment with DXM cough medicine." *Id.* ¶ 17 (quoting E. Catena & L. Daffonchio, "Efficacy and Tolerability of Levodropopizine in Adult Patients with Non-productive Cough, Comparison with Dextromethorphan," 10 Pulmonary

Pharmacology & Therapeutics 89–96 (1997)). That study also indicated that "cases of intense somnolence were related only to dextromethorphan" rather than the other drug addressed in the study. *Id*. (internal quotation marks omitted). In addition, the Complaint notes that study participants "were given an even smaller dosage of DXM . . . than the recommended dose found in many Equate products." *Id*. Goldstein also alleges that the adverse event report database of the U.S. Food and Drug Administration ("FDA") "confirm[s] that 'sedation' is one of the most frequently-cited side effects" of DXM-containing products, and that the Federal Aviation Administration prohibits pilots from flying after ingesting DXM. *Id.* ¶¶ 18–19.

Goldstein alleges that the "Non-Drowsy" representation on the label is false and misleading, noting that FDA regulations prohibit drug labeling that is "false or misleading." *Id*. ¶¶ 20, 24. The Non-Drowsy Equate Products do not disclose anywhere on their packaging that they do or can cause drowsiness or that drowsiness is a side effect of those products. *Id*. ¶ 13. Goldstein alleges that based on the label, a reasonable consumer would believe that the products do not cause drowsiness and would believe that drowsiness is *not* a side effect of the products. *Id*. ¶ 14. For support, Goldstein cites a Consumer Reports article stating that "'Non-drowsy' is code for antihistamines and other medications that don't make you sleepy" and a dictionary definition of non-drowsy as "not causing or accompanied by drowsiness." *Id.* ¶ 21. There is also no language that would "qualify these representations, or that would otherwise put a reasonable consumer on notice of the fact that the Non-Drowsy Equate Products actually cause drowsiness." *Id*. ¶ 22. Moreover, other drug makers who sell products with DXM, such as Mucinex DM, do not claim that their products are non-drowsy. *Id.* ¶ 23. Goldstein alleges that Walmart "could have simply omitted the false and misleading statement, Non-Drowsy," from its products. *Id*. ¶

24. Alternatively, Goldstein states that Walmart could have labeled it as "less drowsy," as other drug makers do for non-DXM products. *Id*. ¶¶ 25–26.

Goldstein alleges that Walmart labels the products "Non-Drowsy" intending to cause consumers to rely upon it and believe that the products would not cause drowsiness, so that they would buy more products or pay more for them. *Id.* ¶¶ 14–15, 56. She further alleges that Walmart's "Non-Drowsy" representation is material to reasonable consumers. *Id*. ¶ 27. In certain situations, consumers prefer OTC drugs that will not make them drowsy to products that may make them drowsy, particularly if they are using them during the day, or if they are planning to engage in activities, such as work, that require them to be alert. *Id*. Indeed, in many situations, taking a drug that does or can cause drowsiness can be dangerous, such as when the customer is or plans to be driving. *Id.* Because customers value the non-drowsiness aspect of the medication, Walmart's false statements increased the demand for the Non-Drowsy Equate Products and allowed them to charge a price premium. *Id.* ¶ 28. Absent the "non-drowsy" label, demand would drop, and the price would be reduced. *Id*. ¶ 29. In addition, because the Non-Drowsy Equate Products actually do cause drowsiness, Plaintiff and each class member did not get what they paid for: a cough medicine that does not cause drowsiness. *Id.* ¶ 30. Goldstein claims that she, and members of her class, sustained economic injuries for these reasons. *Id*. ¶¶ 28, 30, 31.

Goldstein claims that she would not have purchased the Product had she known that it caused drowsiness. *Id*. ¶ 32. She also alleges that the price she paid for the Product was artificially inflated by Defendant's misleading "Non-Drowsy" label and that the Product was worthless to her because it causes drowsiness. *Id*. She also claims that she would purchase Non-Drowsy Equate Products again for non-drowsy use if they were actually "non-drowsy," but since

she faces an "imminent threat of harm" because she cannot rely on the labels, she "will not be able to purchase the products." *Id.* ¶ 33.

II. Federal Regulation of OTC Cough Medicine

The sale in the United States of OTC medications is regulated by the FDA under the Federal Food, Drug, and Cosmetic Act ("FDCA"), 21 U.S.C. § 301 *et seq.* A manufacturer seeking to sell a new drug in interstate commerce may qualify for an FDA determination that the drug is generally recognized as safe and effective ("GRAS/E") by following a "monograph," which is a detailed regulation established by the FDA for each therapeutic class of OTC drug product. *See Natural Res. Def. Council, Inc. v. U.S. Food & Drug Admin.*, 710 F.3d 71, 75 (2d Cir. 2013). A monograph, which is promulgated by the FDA through the notice-and-comment process, sets "the FDA-approved active ingredients for a given therapeutic class of OTC drugs and provides the conditions under which each active ingredient is GRAS/E." *Id.* Monographs identify the active ingredients that can be marketed for certain use, such as cough remedies. 21 C.F.R. § 341.1. In the case of antitussive drug products, the monograph sets forth certain "indications" and "warnings" and "directions" to be included on the label, including a "statement of identity" with the name of the product and the kind of medicine it is. *Id.* § 341.74. Before a monograph is published, an "advisory review panel of qualified experts" "prepare[s] a report containing its conclusions and recommendations to the Commissioner with respect to the safety and effectiveness of the drug." *Id.* § 330.10; *see also* Cold, Cough, Allergy, Bronchodilator, and Antiasthmatic Drug Products for Over-the-Counter Human Use; Final Monograph for OTC Antitussive Drug Products, 52 Fed. Reg. 30,042, 30,055–56 (Aug. 12, 1987). The monograph requires certain antitussive products—but not those made with DXM—to include on the label a warning that the drug may cause drowsiness. 21 C.F.R. § 341.74.

The FDCA prohibits the misbranding of drug. A drug is "deemed to be misbranded [if] its labeling is false or misleading in any particular." 21 U.S.C. § 352. The FDA's regulations also provide that:

> An over-the-counter cold, cough, allergy, bronchodilator, or antiasthmatic drug product in a form suitable for oral, inhalant, or topical administration is generally recognized as safe and effective and *is not misbranded* if it meets each of the conditions in this part and each of the general conditions established in § 330.1.

21 C.F.R. § 341.1 (emphasis added); *see also id.* § 330.1 (providing for "[g]eneral conditions for general recognition as safe, effective, and not misbranded").

PROCEDURAL HISTORY

Plaintiff filed her initial complaint on January 5, 2022. Dkt. No. 1. On March 14, 2022, Plaintiff filed the Complaint. Dkt. No. 15. The Complaint is brought by Plaintiff individually and on behalf of a class of all persons who purchased a Non-Drowsy Equate Product in the United States during the applicable statute of limitations. *Id.* ¶ 34. Plaintiff asserts the following claims: (1) violations of state consumer protection statutes, including N.Y. General Business Law § 349 and the comparable laws of Washington, D.C., Massachusetts, Missouri, Rhode Island, Vermont, and Washington State, on behalf of Plaintiff and a Consumer Protection Subclass, *id.* ¶¶ 44–50; (2) violation of the New York General Business Law § 349 on behalf of Plaintiff individually and a New York Subclass, *id.* ¶¶ 51–58; (3) violation of the New York General Business Law § 350 on behalf of Plaintiff individually and the New York Subclass, *id.* ¶¶ 59–67; (4) breach of express warranty on behalf of Plaintiff and a Nationwide Class, *id.* ¶¶ 68–74; and (5) breach of the MMWA on behalf of Plaintiff and a Nationwide Class, *id.* ¶¶ 75–83.

Defendant filed its motion to dismiss the Complaint on March 28, 2022. Dkt. No. 22. Plaintiff filed its opposition to the motion to dismiss on April 29, 2022, Dkt. No. 27, and

Defendant filed a reply brief in further support of its motion to dismiss on May 11, 2022, Dkt. No. 30. On July 8, 2022, Plaintiff filed a notice of supplemental authority, Dkt. No. 31, and on July 27, 2022, Defendant filed a response to the notice of supplemental authority, Dkt. No. 32. Defendant filed an additional notice of supplemental authority on August 18, 2022, Dkt. No. 34, and Plaintiff filed a response on the same day, Dkt. No. 35. The Court heard oral argument on October 6, 2022.

LEGAL STANDARD

To survive a motion to dismiss pursuant to Federal Rule of Civil Procedure 12(b)(6), a complaint must include "sufficient factual matter, accepted as true, to 'state a claim to relief that is plausible on its face.'" *Ashcroft v. Iqbal*, 556 U.S. 662, 678 (2009) (quoting *Bell Atl. Corp. v. Twombly*, 550 U.S. 544, 570 (2007)). "A claim has facial plausibility when the plaintiff pleads factual content that allows the court to draw the reasonable inference that the defendant is liable for the misconduct alleged." *Id.* "Determining whether a complaint states a plausible claim for relief will . . . be a context-specific task that requires the reviewing court to draw on its judicial experience and common sense." *Id.* at 679. Put another way, the plausibility requirement "calls for enough fact to raise a reasonable expectation that discovery will reveal evidence [supporting the claim]." *Twombly*, 550 U.S. at 556; *accord Matrixx Initiatives, Inc. v. Siracusano*, 563 U.S. 27, 46 (2011). However, although the Court must accept all the factual allegations of a complaint as true, it is "not bound to accept as true a legal conclusion couched as a factual allegation." *Iqbal*, 556 U.S. at 678 (quoting *Twombly*, 550 U.S. at 555). The ultimate issue "is not whether a plaintiff will ultimately prevail but whether the claimant is entitled to offer evidence to support the claims." *Walker v. Schult*, 717 F.3d 119, 124 (2d Cir. 2013) (quoting *Scheuer v. Rhodes*, 416 U.S. 232, 235–36 (1974)); *see also DiFolco v. MSNBC Cable L.L.C.*, 622 F.3d 104, 113 (2d Cir. 2010) ("In ruling on a motion pursuant to Fed. R. Civ. P. 12(b)(6), the

duty of a court is merely to assess the legal feasibility of the complaint, not to assay the weight of the evidence which might be offered in support thereof." (internal quotation marks and citation omitted)).

A court properly dismisses a claim for lack of subject matter jurisdiction under Rule 12(b)(1) when it "lacks the statutory or constitutional power to adjudicate it." *Cortlandt St. Recovery Corp. v. Hellas Telecomms., S.a.r.l.*, 790 F.3d 411, 416–17 (2d Cir. 2015) (citation omitted). "A plaintiff asserting subject matter jurisdiction has the burden of proving by a preponderance of the evidence that it exists." *Makarova v. United States*, 201 F.3d 110, 113 (2d Cir. 2000). "A motion to dismiss for lack of subject matter jurisdiction may 'raise a facial challenge based on the pleadings, or a factual challenge based on extrinsic evidence.'" *U.S. Airlines Pilots Ass'n ex rel. Cleary v. US Airways, Inc.*, 859 F. Supp. 2d 283, 296 (E.D.N.Y. 2012) (quoting *Guadagno v. Wallack Ader Levithan Assocs.*, 932 F. Supp. 94, 95 (S.D.N.Y. 1996)). However, "[a] bare assertion of standing alone will not do." *Monegro v. St. Insider Dot Com Inc.*, 2022 WL 445797, at *2 (S.D.N.Y. Feb. 11, 2022). Although injury may be pleaded generally, *see Lujan v. Defenders of Wildlife*, 504 U.S. 555, 561 (1992), the plaintiff must still allege "facts that affirmatively and plausibly suggest that [the plaintiff] has standing to sue." *Carter v. HealthPort Technologies, LLC*, 822 F.3d 47, 56 (2d Cir. 2016) (quoting *Amidax Trading Group v. S.W.I.F.T. SCRL*, 671 F.3d 140, 145 (2d Cir. 2011)).

DISCUSSION

Defendant argues that: (1) the Complaint must be dismissed because Plaintiff's claims are preempted by the FDCA; (2) Plaintiff's claims alleging violations of laws of states other than the State of New York should be dismissed because she is a New York resident; (3) Plaintiff's claims under New York General Business Law fail because of that law's safe harbor and because Plaintiff has not otherwise plausibly pleaded an injury or that the label is materially misleading;

(4) Plaintiff has not adequately pleaded facts showing that the "non-drowsy" label constitutes an express warranty; (5) Plaintiff fails to allege certain required elements of the MMWA; and (6) Plaintiff lacks standing to pursue injunctive relief. Dkt. No. 22. Defendant also argues, in a footnote, that Plaintiff failed to provide reasonable notice to Defendant after she discovered the alleged breach of the express warranty. *Id*. at 15 n.3. Plaintiff rebuts all contentions. Dkt. No. 27.

For the following reasons, the Court concludes that Plaintiff's claims are preempted under the FDCA. For that reason, the Court concludes that Plaintiff's MMWA claim fails as well and need not reach the sufficiency of Plaintiff's pleadings on her state claims or whether she has statutory standing to pursue non-New York consumer fraud claims . The Court determines that Plaintiff does not have standing to pursue injunctive relief.

I. Preemption

Defendant first argues that Plaintiff's state claims are preempted by the FDCA. Dkt. No. 22 at 6. In particular, Defendant notes that the FDA promulgated a monograph concerning OTC cold and cough medicines, *id.* at 6–7, and that Plaintiff cannot seek to "impose additional labeling requirements not identical to those established by the FDA," *id*. at 8. Plaintiff argues that her claims are not preempted because she is focusing on an affirmative misrepresentation, rather than misrepresentation through omission that would require additional disclosures, Dkt. No. 27 at 3–7, because the FDA never approved the non-drowsy statement, *id.* at 7, and because mere compliance with a monograph does not establish preemption, *id*. at 12–15. For the following reasons, the Court concludes that Plaintiff's claims are preempted under the FDCA.

A. The FDCA Preemption Provision

"The key to the preemption inquiry is the intent of Congress. Congress may manifest its intent to preempt state or local law explicitly, through the express language of a federal statute,

or implicitly, through the scope, structure, and purpose of the federal law." *New York SMSA Ltd. P'ship v. Town of Clarkstown*, 612 F.3d 97, 103 (2d Cir. 2010) (citing *Altria Grp., Inc. v. Good*, 555 U.S. 70, 76 (2008)). "[W]here . . . Congress has expressly manifested its intent to preempt state law, no presumption against preemption arises." *Canale v. Colgate-Palmolive Co.*, 258 F. Supp. 3d 312, 319 (S.D.N.Y. 2017). Rather, courts "focus on the plain wording of the clause, which necessarily contains the best evidence of Congress' preemptive intent." *Id.* (quoting *Chamber of Commerce of the U.S. v. Whiting*, 563 U.S. 582, 594 (2011)).

The FDCA contains an express preemption clause for nonprescription drugs. The clause preempts "requirements" that are "different from or in addition to" or "otherwise not identical with" the FDCA. The full text of the relevant subsection reads as follows:

> [N]o State or political subdivision of a State may establish or continue in effect any requirement—(1) that relates to the regulation of a drug that is not subject to the requirements of section 353(b)(1) or 353(f)(1)(A) of this title; and (2) is different from or in addition to, or that is otherwise not identical with, a requirement under this chapter.

21 U.S.C. § 379r(a). "[T]he term 'requirements' . . . reaches beyond positive enactments, such as statutes and regulations, to embrace common-law duties." *Bates v. Dow Agrosciences LLC*, 544 U.S. 431, 443 (2005). "A requirement is a rule of law that must be obeyed. . . . The proper inquiry calls for an examination of the elements of the common-law duty at issue . . . ; it does not call for speculation as to whether a jury verdict will prompt the manufacturer to take any particular action." *Id.* at 445; *see also Mut. Pharm. Co. v. Bartlett*, 570 U.S. 472, 492 (2013) (same); *Goldemberg v. Johnson & Johnson Consumer Companies, Inc.*, 8 F. Supp. 3d 467, 474 (S.D.N.Y. 2014) (applying *Bates* in terms of the term "requirement" in the FDCA's preemption provision for cosmetics). A common law rule that "requires that manufacturers label or package their products in [a] particular way" qualifies as a requirement with respect to labeling. *Bates*, 544 U.S. at 444.

Product liability claims are exempt from preemption under the statute. The FDCA provides that "[n]othing in this section shall be construed to modify or otherwise affect any action or the liability of any person under the product liability law of any State." 21 U.S.C. § 379r(e); *see also Wyeth v. Levine*, 555 U.S. 555, 575 (2009) ("In 1997, Congress pre-empted certain state requirements concerning over-the-counter medications and cosmetics but expressly preserved product liability actions.").[2]

The legislative history of the Food and Drug Administration Modernization Act of 1997—the bill that established the preemption provision at issue—reveals numerous purposes behind the preemption clause. The accompanying Senate Report to the bill explained that:

> Under our Federal system, it is important that State and local officials enforce the same regulatory requirements for products as do our Federal officials. Different or additional requirements as the State or local level can work against our national marketplace, confuse consumers, raise prices, undermine public confidence in our regulatory system and in products important to the public health, and result in divergent public health protection throughout the country.
>
> Federal law currently provides strong public health protection for nonprescription drugs and cosmetics and their constituents. Nonprescription drugs are subject to careful and comprehensive regulation by the FDA. The conditions under which nonprescription drugs are considered safe and effective, for use by the lay consumer, are specified by FDA in nonprescription drug monographs or by new drug and antibiotic drug applications. FDA also ensures that the labeling of nonprescription drugs provides adequate directions for use, and adequate warnings against unsafe use, through these monographs and drug marketing applications, as well as through a number of general and specific labeling regulations. . . . The FDA authority in this area extends from manufacture through retail sale of these products.
>
> Section 808 of the legislation therefore established a new section 761 of the Federal Food, Drug, and Cosmetic Act that adopts, as a general rule, the requirement of national uniformity in the regulation of nonprescription drugs and cosmetics and

[2] Although not directly at issue here, the statute also carves out exemptions for state "requirements" following application by a state to the FDA and a subsequent notice and comment process if such requirement meets the standards of "protect[ing] an important public interest that would otherwise be unprotected," "not caus[ing] any drug to be in violation of any applicable requirement or prohibition under Federal law," and "not unduly burden[ing] interstate commerce." 21 U.S.C. § 379r(b).

their constituents. No State or local government is permitted to impose different or additional requirements that relate to the subject matter covered by the three Federal laws as they apply to nonprescription drugs and cosmetics. These include requirements imposed on product manufacture or composition, labeling, advertising, or any other form of public notification or communication.

. . .

Under the legislation, all States may vigorously enforce requirements for nonprescription drugs and cosmetics that are identical to the Federal requirements, including the Federal prohibition against the adulteration or misbranding of these products. Most States have enacted laws regulating nonprescription drugs and cosmetics, based on the Federal laws, that prohibit the adulteration or misbranding of these products in the same terms as the Federal laws. These identical State requirements may be enforced by State officials, without first notifying the FDA or obtaining any Federal approval . . . . Accordingly, one consistent national regulatory system will be implemented, relying upon both Federal and State enforcement, providing strengthened public health protection throughout the country.

. . .

A State, locality, or person may continue to take advantage of their right to petition the FDA, where it has not issued a regulation, to make a certain requirement a national requirement, under the right supplied to them in 21 CFR 10.30, the citizen petition provision of the Code of Federal Regulations.

The FDA jurisdiction relating to dissemination of information about nonprescription drugs and cosmetics and their constituents applies to the label and labeling for these products. It is important that any State or local requirements imposed on industry relating to the advertising of nonprescription drugs or cosmetics, or to any other form of public notification or communication relating to these products and their constituents, be identical with the FDA requirements for the label and labeling of these products. Accordingly, the legislation extends national uniformity to the requirements for all forms of public information and public communication, not just to the label and labeling.

. . .

Under the legislation, national uniformity is provided for all of the types of requirements for nonprescription drugs and cosmetics and their constituents under State laws that are related to requirements included in the Federal laws, e.g., requirements to prevent adulteration or misbranding or other illegal marketing or to issue public notice about the safety of constituents. . . . Under the legislation, national uniformity is provided for all of the types of requirements for nonprescription drugs and cosmetics and their constituents under State laws that are related to requirements included in the Federal laws, e.g., requirements to prevent

> adulteration or misbranding or other illegal marketing or to issue public notice about the safety of constituents.
>
> Finally, the legislation explicitly provides that it shall not be construed to modify or otherwise affect the traditional product liability law of any State. Tort liability rules and requirements would remain unchanged and unaffected.

S. Rep. No. 105-43, 105th Cong. 47, P.L. 105-115, Accountability Act of 1997 (July 1, 1997), 1997 WL 394244 at *64.[3] Of relevance here, the accompanying House Conference Report primarily discussed the effect of the preemption requirement on "Little FTC" laws, stating that

> The Conference Committee intends to make clear that "Little FTC" laws, as they have historically been written and applied, are not preempted. The scope of national uniformity is modified to only apply to state requirements that relate to labeling and packaging or, if they go beyond labeling and packaging, to requirements relating to warnings. Thus, advertising issues relating to claims substantiation, fair balance, and misleading or deceptive claims are outside the scope of preemption.

H.R. Conf. Rep. 105-399, 103, P.L. 105-115, Food and Drug Administration Modernization Act of 1997 (Nov. 9, 1997), 1997 U.S.C.C.A.N. 2880, 2893. New York General Business Law § 349 is one such "Little FTC" Act. *See Safe Step Walk in Tub Co. v. CKH Indus., Inc.*, 242 F. Supp. 3d 245, 261 (S.D.N.Y. 2017).

B. Relevant Caselaw

Defendant relies on a series of cases to establish that Plaintiff's claims are preempted. The most relevant Circuit precedent is *Critcher v. L'Oreal USA, Inc.*, 959 F.3d 31 (2d Cir. 2020). There, the plaintiffs were consumers of beauty products alleging that the creams they had bought were not fully accessible from their respective containers. *Id*. at 33. The complaint "allege[d]

[3] Although the Senate Report accompanied an earlier version of the bill that became the Modernization Act, the relevant language in the preemption clause that "no State or political subdivision of a State may establish or continue in effect any requirement . . . that relates to a [nonprescription] drug . . . and . . . that is different from or in addition to, or that is otherwise not identical with, a requirement of this Act" from that preliminary version was consistent in all versions of the bill and included in the final bill that became law. S. Rep. No. 105-43, 1997 WL 394244 at *155.

that the[] injuries resulted from the fact that the labels of the various L'Oréal products omitted certain critical information—specifically, that the creams could not be fully dispensed." *Id.* at 36. Plaintiffs argued that "while the containers accurately state the total amount of product contained . . . , [d]efendant fails to disclose to consumers that they will not be able to access or use a large percentage . . . of the product purchased." *Id.* at 36 (quoting the plaintiffs' complaint). In other words, the plaintiffs in *Critcher* had argued that "mere compliance with that net-quantity disclosure requirement is not enough because it . . . has the effect of making the packaging misleading [because] a consumer will think that the amount identified on the label is the amount that is accessible." *Id.* Plaintiff had thus "assert[ed] that compliance with one part of the FDCA and its regulations counterintuitively results in a violation of another part of the FDA." *Id.* Therefore, "[i]n order for L'Oréal—or any similarly situated cosmetic producer—to avoid liability under Plaintiffs' theory, then, L'Oréal must make an additional disclosure on its packaging." *Id.*

The Circuit concluded that this "theory [of liability]" "does not" "survive the FDCA preemption clause" because it would be "using state law to impose labeling requirements on top of those already mandated in the FDCA and the regulations promulgated thereunder." *Id.* The Circuit, in assessing the effect of a substantially similar express preemption provision of the FDCA with respect to cosmetics,[4] noted that "[t]he FDCA preempts not only those state laws that are in conflict with it (*i.e.*, any law that is 'different from' the FDCA), but also *any* state law

[4] That preemption provision provides that "no State or political subdivision of a State may establish or continue in effect any requirement for labeling or packaging of a cosmetic that is different from or in addition to, or that is otherwise not identical with, a requirement specifically applicable to a particular cosmetic or class of cosmetics under this chapter, the Poison Prevention Packaging Act of 1970 (15 U.S.C. 1471 *et seq.*), or the Fair Packaging and Labeling Act (15 U.S.C. 1451 *et seq.*)." 21 U.S.C. § 379s.

that provides for labeling requirements that are not *exactly the same* as those set forth in the FDCA and regulations (*i.e.*, any law that is 'in addition to' the FDCA)." *Id.* at 35–36 (emphasis in original). The Circuit concluded that "Congress or the FDA could have chosen to mandate such additional labeling when they established the comprehensive regulatory regime governing cosmetics, but they did not," and that "plaintiffs cannot now seek to impose those requirements through alternative means grounded in state law." *Id.* at 36.

The Circuit cited favorably three cases from district courts to support its conclusion. *Id.* at 37 n.24. One of those cases from this District is *Bimont v. Unilever U.S., Inc.*, 2015 WL 5256988 (S.D.N.Y. Sept. 9, 2015). Defendant also relies on *Bimont* in its motion to dismiss. Dkt. No. 22 at 10. There, plaintiffs sued Unilever alleging that its packaging of deodorant had "misstate[d] the 'actual weight of usable product' in each stick of deodorant . . . [and] the 'total net weight' . . . and . . . contain[ed] 'non-functional slack-fill . . . , caus[ing] the false impression that there was more product than actually packaged.'" *Id.* at *1 (quoting the complaint). The parties agreed that the products were both cosmetics and OTC drugs. *Id.* at *2 n.3. The court held that while "[a] state law that applies to drugs or cosmetics is preempted if it imposes a requirement that is not identical to the requirements of the FDCA and the FDA's regulations," there is "a caveat: preemption does not preclude a state-law claim if the state requirement is outside the scope of the relevant federal requirements." *Id.*; *see also O'Connor v. Henkel Corp.*, 2015 WL 5922183, at *5 (E.D.N.Y. Sept. 22, 2015) (the other district court case cited by the Circuit in *Critcher* for its proposition that "plaintiffs can escape the preemptive force of the FDCA only if their claims seek to impose requirements that (1) are identical to those imposed by the FDCA, or (2) are outside the scope of the relevant federal requirements"). The court noted that there appears to be disagreement on the "degree of distinction from federal law that is

permissible" to be outside the scope of federal requirements. *Bimont*, 2015 WL 5256988, at *3. The court then described three basic formulations of "if they (1) impose any non-identical requirement on *conduct that could be regulated* by the FDA . . . (2) impose any non-identical requirement on *conduct whose subject matter has been regulated* by the FDA; or (3) impose any *conflicting requirement* on conduct that has been regulated by the FDA." *Id*. (emphasis added).

The court concluded—and the Circuit appeared to confirm in *Critcher*—that the third formulation must be incorrect, because it would fail to give any meaning to the term "identical" in the preemption statute. *Id*. at *4. The statutory language prohibiting requirements "different from" was sufficient in itself to address all state laws that impose a "conflicting requirement." If the phrase "otherwise not identical with" was to be accorded any independent meaning, it would have to encompass the imposition of State requirements that were not identical to those within the scope of federal law, and not simply conflicting requirements. *Id.*; *see also C.K. Lee v. Mondelez International Inc. & Mondelez Global LLC*, No. 22-cv-1127, Dkt. No. 36 at 8 n.1 (explaining the exhaustive scope of the phrase "not identical to" in the food preemption context); 21 C.F.R. § 100.1(c)(4) (construing the phrase "not identical to" in the context of food labeling requirements, as essentially those requirements that are "not imposed or contained in the applicable provision" or "differ from those specifically imposed by or contained in the applicable provision"). The *Bimont* court held that, in light of Congress's "specific invitation [to the FDA] to regulate slack-fill in foods, drugs, and cosmetics," the agency's determination not to regulate slack-fill in drugs and cosmetics constituted a decision that "slack-fill in those products [are] insufficiently misleading to warrant regulation," which was "tantamount to a conscious decision by the agency to permit slack-fill." *Id*. at *6 (internal quotation marks and citation omitted).

Concluding that the claims at issue were preempted under both the first and the second approaches, the court did not "resolve the tension" between those approaches. *Id*. at *4.

The *Bimont* court considered four cases to determine how to define the scope of federal requirements. Three of the cases were decided by judges in this District—*Bowling v. Johnson & Johnson*, 65 F. Supp. 3d 371 (S.D.N.Y. 2014), *In re PepsiCo, Inc., Bottled Water Mktg. & Sales Pracs. Litig.*, 588 F. Supp. 2d 527 (S.D.N.Y. 2008), and *Ault v. J.M. Smucker Co.*, 2014 WL 1998235 (S.D.N.Y. May 15, 2014).[5] A fourth case, *Canale v. Colgate-Palmolive Co.*, 258 F. Supp. 3d 312 (S.D.N.Y. 2017), is also relevant.

The first case analyzed by *Bimont*, *Bowling*, provides the broadest and most stringent test for determining if a claim falls within the scope of federal requirements and thus is preempted. In *Bowling*, the plaintiffs had alleged that the defendant had misbranded mouthwash by labeling it as "restore[s] enamel." *Bowling*, 65 F. Supp. 3d at 373. The FDA had never expressed any concern about the label "restore[s] enamel" and the relevant monograph simply contained language that such products could prevent tooth decay. *Id*. at 373–74. The court determined that while preemption is "certainly appropriate when a state law prohibits labeling that is permitted under federal law. . . . it is also appropriate when a state law prohibits labeling that is *not prohibited* under federal law." *Id*. at 375. "[I]n other words, [the test] is not whether a state law actively undermines federal law. It is whether state law diverges from federal law *at all*." *Id*. (emphasis in original). Thus, in the view of the *Bowling* court, the plaintiffs were required to "plead facts suggesting that the FDA has affirmatively prohibited the label. Otherwise,

[5] The *Bimont* court also briefly considered *Astiana v. Hain Celestial Grp., Inc.*, 783 F.3d 753, 757 (9th Cir. 2015), but this Court need not assess *Astiana* in detail—not only because it is not binding on this Court, but also because for the issue in that case, which concerned the label "natural" on cosmetics, no party had shown that the FDA had addressed that subject matter through any requirement.

plaintiffs' state law causes of action would be, in effect, imposing a labeling requirement that is 'not identical with' labeling requirements under federal law." *Id*. at 376. The court concluded that while the "case might be different if the FDA had issued no guidance as to dental hygiene products, making it possible to conclude that [Listerine] falls beyond the scope of federal regulation entirely," "the FDA has issued a monograph directly on point but declined, in spite of that, to indicate . . . that 'Restores Enamel' is misleading." *Id*. at 376. The court thus held the claim to be preempted. *Id*.

PepsiCo offers a narrower scope of preemption and a more permissive standard for state requirements. In *PepsiCo*, the plaintiffs alleged that defendant "misrepresented the source of Aquafina water by using a label designed to create the impression that the water came from a mountain source and failing to inform consumers that the true source . . . [was] tap water." 588 F. Supp. 2d at 529. Plaintiffs argued that "[d]efendants may be held liable under state law for failing to disclose the source of Aquafina water." *Id*. at 534. The court concluded that such claims were preempted because "the FDA specifically addressed the disclosure of source information and determined, in its expert opinion, that representations of source are immaterial in the context of purified water," even if the water came from tap water. *Id*. "Consequently, Plaintiffs' claims are expressly preempted under both of their theories because: (1) federal law is not silent on the subject of implied labeling misrepresentations regarding the municipal source of bottled water; and (2) given that the Aquafina label fits within the exception for purified water and thus complies with the FDCA's requirements, Plaintiff's state law claims by necessity are premised on requirements that are not parallel to those imposed by federal law." *Id*. at 537. In other words, the FDA having considered the issue, determined not to require the disclosure of

source information and thus the claims seeking to impose liability due to the failure to disclose that source were expressly preempted.

In *Ault*, the defendant argued that claims of misleading representations regarding the label "All Natural" under state law were conflict-preempted by FDA policies regarding bioengineered foods. The court rejected that argument, although it did not specifically base its decision on the terms of the express preemption clause. *Ault*, 2014 WL 1998235, at *2. The FDA had expressly represented to the *Ault* court in a letter that it had "declined to consider the specific issue," *id.* at *3, of "whether and under what circumstances food products containing ingredients produced using genetically engineered ingredients may or may not be labeled 'natural,'" *id*. (quoting the FDA letter). There was thus no question that "no federal specifications exist[ed] [t]here." *Id*. *Ault* also distinguished *PepsiCo* by stating that "[p]laintiff does not claim that [d]efendant misrepresented the list of ingredients in Crisco Oil; rather, [p]laintiff claims that the use of the phrase 'All Natural' is misleading to describe foods containing GMOs and that no FDA regulations specifically address this representation." *Id*. at *4. The *Ault* court mentioned that "*In re PepsiCo* distinguished a case that held that claims regarding Poland Spring's marketing of its water as 'pure' were not preempted because no federal standard of identity for bottled water purity existed." *Id*. The court concluded that "[s]ince no federal standard exists for the use of the phrase 'All Natural,' Defendant's reliance on *PepsiCo* is unavailing." *Id*.

Finally, in *Canale*, which the *Bimont* Court did not expressly analyze, the plaintiff brought claims related to the representations regarding the whitening effect of toothpastes. *Canale*, 258 F. Supp. 3d at 316. Judge Seibel—the same judge who decided *PepsiCo*—concluded that these claims were not preempted. She stated that "[w]here federal law

specifically regulates the subject matter of a plaintiff's state law claims, and those claims seek to impose requirements not identical to federal requirements, those state law claims are preempted." *Id*. at 320. She concluded that none of the federal requirements, however, addressed "the whitening capabilities of hydrogen peroxide." *Id*. at 321. First, "[t]here [wa]s nothing in the [relevant] monograph regarding whitening toothpastes or products." *Id*. Second, the other regulatory material cited by plaintiff—a tentative, nonfinal monograph—concerned "temporary surface teeth staining caused by products containing stannous fluoride," "not stains ostensibly ameliorated by hydrogen peroxide." *Id*. at 322. And while the FDA had denied a citizen petition from a professional dentist association concerning individuals using teeth-whitening products without consulting a dentist, the document indicated that the "FDA believed it did not have sufficient information regarding peroxide-containing teeth whiteners to determine whether they should be regulated as OTC drugs, and thus declined to put forth any requirements in addition to those already applicable because of teeth whiteners' status as cosmetics." *Id*. "The denial does not, as Defendant claims, address the *substance of any representations* about the whitening effect of peroxide-containing products." *Id*. (emphasis added).

C. Application

Plaintiff's claim does not fall "*outside the scope* of federal requirements, which would allow the claims to proceed," *Bimont*, 2015 WL 5256988, at *4 (emphasis added); *see also Good*, 555 U.S. at 76 ("If a federal law contains an express pre-emption clause, it does not immediately end the inquiry because the question of the substance and scope of Congress' displacement of state law still remains."). This case is more like *PepsiCo* and *Bowling* than like *Ault* or *Canale*.

The current monograph deals squarely with the issue of whether DXM requires a drowsiness warning. The FDA has determined that other antitussives containing

diphenhydramine citrate or diphenhydramine hydrochloride must bear a warning on their labels that they, for example, "[m]ay cause marked drowsiness." 21 C.F.R. § 341.74(c)(4)(viii)–(ix). In the same monograph, the FDA specified the warnings required for oral antitussives containing DXM. Those warnings include "[d]o not use if you are now taking a prescription monoamine oxidase inhibitor (MAOI) (certain drugs for depression, psychiatric, or emotional conditions, or Parkinson's disease)." *Id*. § 341.74(c)(4)(v)–(vi). The FDA tellingly did not require a warning on oral antitussives that contain DXM that they may cause drowsiness. In promulgating the monograph, the FDA noted its "recognition" of "scientific literature describ[ing a] slight drowsiness as a side effect for both codeine and dextromethorphan." It nonetheless stated that "[it] is not aware of data demonstrating that the antitussive ingredients codeine and dextromethorphan . . . require a drowsiness warning." Cold, Cough, Allergy, Bronchodilator, and Antiasthmatic Drug Products for Over-the-Counter Human Use; Tentative Final Monograph for OTC Antitussive Drug Products, 48 Fed. Reg. 48576-01, 48589 (Oct. 1, 1983). It therefore concluded that, unlike the other products that required a label "[m]ay cause marked drowsiness," "sleep-aid claims directly related to the ability to the ability of an antitussive ingredient to cause drowsiness, e.g., 'For relief of occasional sleeplessness.' will remain in Category III," a category that required further testing but not a warning. *Id*. at 48577. Thus, the FDA considered whether products containing DXM required a drowsiness warning and concluded that more data was needed before such a warning should be given. In summary, the FDA considered Plaintiff's claim that DXM caused drowsiness and determined that insufficient data existed to support such a finding. This passes the more stringent test under *Bowling* as well as the less stringent test in *PepsiCo* and *Canale*.

Plaintiff makes several arguments in response. First, it claims that it is not seeking to require Defendant to include language on its label different from what the FDA would require, but simply not to include certain language that the FDA has not required the label to include. Plaintiff thus seeks to draw a distinction between a misrepresentation claim, such as the one it makes, which challenges the inclusion of allegedly objectionable language, and an omission claim that challenges the failure to include language. It argues that, even if the latter type of claim is preempted, the former—which can be remedied by removing the objectionable language—is not. But the distinction between an omission claim and a misrepresentation claim is notoriously elusive. Virtually every omission claim could be repackaged as a misrepresentation claim. Consider, for example, a manufacturer who sells its cough medicine in a bright orange package with a blazing sun in the forefront. The orange labelled bottle is silent with respect to whether it causes drowsiness or is for daytime or nighttime use. The failure to include a warning that the product might put the consumer to sleep could well be framed as an omission, and so framed, would be preempted even under Plaintiff's theory—the lawsuit could be read to require the manufacturer to include language that the FDA did not require, and not simply to remove language that the FDA did require. But that identical claim easily could be reframed as one of misrepresentation. A reasonable consumer would be given the impression from the orange labeling with a sun that the product was designed to be used when the consumer needed to be awake. As *PepsiCo* demonstrates, even an image or a color—if not accompanied by curative or clarifying language—can be argued to convey a misleading impression. *See*, *e.g.*, *Budhani v. Monster Energy Co.*, 527 F. Supp. 3d 667, 680 (S.D.N.Y. 2021) (holding that flower imagery on a product label and its context suggested that the product contained extract from vanilla bean). The only way for the manufacturer to avoid liability would be to "make an

additional disclosure on its packaging." *Critcher*, 959 F.3d at 36. The point need not be limited to an orange label. Even the representation that a product is "cough medicine" could be argued to be misleading if, in fact, the product does not just suppress coughs but puts the patient to sleep. The point is that preemption cannot be addressed by facile reference to whether a claim sounds in affirmative misrepresentation or misleading omission. In this context, the distinction between a claim of affirmative misrepresentation and misrepresentation by omission is one "without a difference." *Amara v. Publix Supermarkets, Inc.*, 2022 WL 3357575, at *4 (M.D. Fla. Aug. 15, 2022); *see also* Restatement (Second) of Torts, § 529, cmt. a (1977) ("A statement that contains only favorable matters and omits all reference to unfavorable matters is as much a false representation as if all the facts stated were untrue.").

Thus, while the lawsuit in *Critcher* was framed as one seeking additional disclosure, the court's statement of law regarding preemption under the FDCA was not so limited. The court held that the preemption clause preempts "*any* state law that provides for labeling requirements that are not *exactly the same* as those set forth in the FDCA and regulations (*i.e.*, any law that is 'in addition to' the FDCA)." *Critcher*, 959 F.3d at 34–35 (emphasis in original). This expansive language encompasses the duties that the Plaintiff seeks to impose here through state law. As previously noted, Plaintiff's state law claims seek an imposition of a "requirement," within the meaning of *Bates*, that is "in addition to" and "not identical with" those in the FDCA and thus is preempted. 21 U.S.C. § 379r(a).

Plaintiff also contends that the "non-drowsy" representation has not been regulated, or approved, by the FDA and thus a claim that its inclusion on a product is misleading would fall outside the scope of the regulations that are preempted by the FDA. Dkt. No. 27 at 7. To be sure, "the term 'Non-Drowsy' . . . is not specifically mentioned in the regulations," Dkt. No. 22

at 10, nor has the Court independently identified any mention of the "non-drowsy" label in the relevant monograph, *see generally* 21 C.F.R. § 341.74. But the FDA need not have dealt with the specific representation at issue in order to have "regulated" "the subject matter," *Bimont*, 2015 WL 5256988, at *5, of the alleged misrepresentation, or the "substance of [the] representation," *Canale*, 258 F. Supp. 3d at 322; *see also Mondelez International, Inc.*, No. 22-cv-1127, Dkt. No. 36 at 8 n.1, 12 (describing similar preemptive scope of FDCA provision governing food labeling claims). Here, as noted, the FDA required a "may cause drowsiness" label with some products and considered whether it should require a similar label with DXM products. It concluded it need not. The subject of whether cough medicines with DXM should carry a drowsiness label thus was explicitly considered by the FDA.

The cases upon which Plaintiff relies thus are distinguishable. In *Canale*, "[t]here [wa]s nothing in the [relevant] monograph regarding whitening toothpastes or products." *Canale*, 258 F. Supp. 3d at 321–22. The citizen petition in *Canale* did not deal with labeling representations, or even the efficacy of those tooth whitening products, but whether tooth whitening products should be classified as drugs based on their mechanism of action (as well as safety concerns). Here, the FDA had sufficient evidence to reach a substantive conclusion that the extant information was not enough to find that DXM required a drowsy warning or to allow a sleep-aid label. The denial of any warning or any ability to market the antitussives as a sleep aid, in contrast, "address[ed] the subject matter" of Plaintiff's alleged misrepresentation of "non-drowsiness"—that is, whether DXM actually makes its users drowsy—and thus is within the scope of "conduct whose subject matter has been regulated by the FDA." *Bimont*, 2015 WL 5256988, at *3.[6]

[6] Plaintiff also contended at oral argument that its claims were "identical" to federal requirements

The remainder of the cases that Plaintiff cites do not acknowledge recent Supreme Court caselaw on express preemption provisions or adopt a mistaken conflict preemption analysis. To the extent that Plaintiff relies on *Geffner v. Coca-Cola Co.*, 343 F. Supp. 3d 246, 251 (S.D.N.Y. 2018), that case construed the express preemption statute in a manner that relied explicitly on a presumption against preemption—a proposition of law that was no longer tenable in the wake of Supreme Court preemption jurisprudence. *See, e.g., Puerto Rico v. Franklin California Tax-Free Tr.*, 579 U.S. 115, 125 (2016) ("[B]ecause the statute 'contains an express pre-emption clause,' we do not invoke any presumption against pre-emption but instead 'focus on the plain wording of the clause, which necessarily contains the best evidence of Congress' pre-emptive intent.'" (quoting *Chamber of Commerce of United States of America v. Whiting*, 563 U.S. 582, 594 (2011))). And with respect to *Ault*, that decision contains some language that a mere removal of the misleading "All Natural" labeling "cannot conflict with FDA labeling requirements" and thus "is not a preempted theory." *Ault*, 2014 WL 1998235, at *3. But in *Ault* the FDA represented that it had "declined to consider the specific issue," *id.*, and the decision does not even mention, let alone interpret, the express preemption clause. The Court agrees with

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because it was "identical" to the FDCA provision that a manufacturer may not use labeling that "is false or misleading in any particular." 21 U.S.C. § 352(a)(1); *see also* 21 C.F.R. § 341.1 (stating that OTC cough and cold drugs "is not misbranded if it meets each of the conditions in this part and each of the general conditions established in § 330.1"); *id.* § 330.1 (stating that one condition is if the product is labeled "in compliance with chapter V of the FDCA," which includes § 352(a)(1)). That argument is not persuasive. Section 379r(a)(2) prevents a state from imposing a labeling requirement that "is different from or in addition to, or that is otherwise not identical with, *a* requirement *under this chapter*," not just the requirement under Section 352(a)(1) that a representation not be misleading. 21 U.S.C. § 379r(a)(2) (emphasis added). Requirements under this chapter include those imposed by monograph—that is the point of the preemption provision. Indeed, taken to its extreme but logical limit, Plaintiff's argument would permit a state to restrict a manufacturer from using any language the state deemed to be false or misleading, or to require a manufacturer to include any language it deemed necessary to make a representation not false or misleading, even if the language that the states would restrict was language that the FDA would require.

the *Bimont* court that reading the express preemption clause to suggest conflict preemption essentially reads out the term "identical" from its plain language.

Finally, Plaintiff argues that holding her claim to be preempted would allow for a parade of horribles—such as "allow[ing] companies to market toys slightly larger than the threshold dimensions . . . and affirmatively claim . . . 'NOT A CHOKING HAZARD.'" Dkt. No. 27 at 9. But there is no particular reason to believe such a parade will follow. Preemption is limited to those representations that fall within a subject that the FDA has regulated. If the FDA has not regulated the subject, then the claim is not preempted. And, if the subject has been regulated, there is no particular reason to believe that this Court—or any court in a proceeding involving two litigants—would come to a more informed conclusion regarding the label that should be put on a product than the FDA would after a notice-and-comment proceeding in which all interested parties have an opportunity to participate. What is certain is that the regime Plaintiff suggests would lead precisely to the patchwork of inconsistent packaging regulations that Congress sought to prevent. If, as Plaintiff suggests, the FDA has come to the incorrect conclusion in its consideration of whether DXM causes drowsiness, Plaintiff can also engage in a citizen petition. If this were not enough, Congress in the FDCA expressly provided an exception to preemption for product liability claims. 21 U.S.C. § 379r(e). And, in addition, if the issue is concerning enough, the FDCA also provides that States may apply for an exemption from the FDCA as well. *Id*. § 379r(b). Accordingly, Plaintiff's GBL claims and his warranty claims are preempted.[7]

[7] Neither of the parties briefed whether the Plaintiff's express warranty claim is a product liability claim that is not preempted under the savings clause of 21 U.S.C. § 379r(e), which provides that "[n]othing in this section shall be construed to modify or otherwise affect any action or the liability of any person under the product liability law of any State." *Id*. At oral argument, Defendant asserted that all of Plaintiff's state law claims—including the express warranty claim—was preempted. In its briefing, Defendant appears to argue the same. *See, e.g.*, Dkt. No. 22 at 6. Plaintiff did not dispute this contention at oral argument, and did not do so in

II. Standing for Injunctive Relief

Defendant contends that Plaintiff does not have Article III standing to pursue injunctive relief. Dkt. No. 22 at 17. In particular, Defendant contends that the "Complaint does not allege any facts explaining how Plaintiff could be injured by *not* buying products she would choose not

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her briefing, making no mention of Section 379r(e). Plaintiff thus has abandoned the claim. Even if Plaintiff had not abandoned it, the Court would conclude that the express warranty claim is preempted. At issue is whether Plaintiff's breach of express warranty claim is premised upon "product liability law" if she alleges purely economic injury, as she does here, and not injury to her person or property. It is a canon of statutory construction that "where Congress borrows terms of art in which are accumulated the legal tradition and meaning of centuries of practice, it presumably knows and adopts the cluster of ideas that were attached to each borrowed word in the body of learning from which it was taken and the meaning its use will convey to the judicial mind unless otherwise instructed. In such case, absence of contrary direction may be taken as satisfaction with widely accepted definitions, not as a departure from them." *Morissette v. United States*, 342 U.S. 246, 263 (1952). "Product liability" is one of those terms. At the time of the passage of the legislation in 1997 encompassing the preemption clause, the consensus was that "product liability" actions do not include those for pure economic loss, as those fall more into the realm of contract law. *See* Restatement (Third) of Torts: Prod. Liab. § 21 (1998) ("Harm to persons or property includes economic loss if caused by harm to: (a) the plaintiff's person; or (b) the person of another when harm to the other interferes with an interest of the plaintiff protected by tort law; or (c) the plaintiff's property other than the defective product itself."); *id.* cmt a. ("Some categories of loss, including those often referred to as 'pure economic loss,' are more appropriately assigned to contract law and the remedies set forth in Articles 2 and 2A of the Uniform Commercial Code."); *see also E. River S.S. Corp. v. Transam. Delaval, Inc.*, 476 U.S. 858, 868–69 (1986) ("Obviously, damage to a product itself has certain attributes of a products-liability claim. But the injury suffered—the failure of the product to function properly—is the essence of a warranty action, through which a contracting party can seek to recoup the benefit of its bargain."); Restatement Third, Torts: Products Liability—Economic loss, 1 Owen & Davis on Prod. Liab. § 6:36 (4th ed.) ("In the early years of products liability in America, in the 1960s and 1970s, courts were split on whether the Restatement Second, Torts § 402A should apply to "pure" economic loss . . . . Over time, courts have moved strongly toward the position that strict products liability in tort should not apply to such pure economic losses that, instead, should be addressed by the law of contract. Adopting this majority position, the Products Liability Restatement provides for the recovery of compensatory damages for personal injury, consortium losses to family members, property damage, and economic loss flowing therefrom, but not for pure economic loss."). The courts to have decided this question thus appear to have concluded that "product liability law" does not include pure economic loss actions. *See, e.g.*, *In re Zantac (Ranitidine) Prod. Liab. Litig.*, 512 F. Supp. 3d 1278, 1297 (S.D. Fla. 2021) (concluding that federal law defines "product liability law," for the purposes of Section 379r(e), as excluding claims of pure economic loss). *But see Voss v. Black & Decker Mfg. Co.*, 450 N.E.2d 204, 207 (N.Y. 1983) (describing breach of express warranty as one of four ways to bring a product liability action).

to buy because she is concerned they may cause drowsiness." *Id*. at 18. Plaintiff responds that she "wishes to re-purchase the Walmart products" and that she argues for a "particular theory of future harm." Dkt. No. 27 at 24. For the following reasons, the Court concludes that Plaintiff does not have standing to assert injunctive relief.

"Under Article III of the U.S. Constitution, '[t]he judicial Power of the United States' extends only to certain 'Cases' and 'Controversies.'" *Lacewell v. Off. of Comptroller of Currency*, 999 F.3d 130, 141 (2d Cir. 2021) (alteration in original) (quoting U.S. Const. art. III, §§ 1–2). In order to invoke federal judicial power, "[t]he plaintiff must have (1) suffered an injury in fact, (2) that is fairly traceable to the challenged conduct of the defendant, and (3) that is likely to be redressed by a favorable judicial decision." *Spokeo, Inc. v. Robins*, 578 U.S. 330, 338 (2016). To maintain an action for injunctive relief, a plaintiff "cannot rely on past injury to satisfy the injury requirement but must show a likelihood that he or she will be injured in the future." *Deshawn E. by Charlotte E. v. Safir*, 156 F.3d 340, 344 (2d Cir. 1998) (citing *City of Los Angeles v. Lyons*, 461 U.S. 95, 105–06 (1983)). Such injury must be "actual and imminent, not conjectural or hypothetical." *Summers v. Earth Island Institute*, 555 U.S. 488, 493 (2009).

The Court finds that the Circuit precedent of *Berni v. Barilla S.p.A.*, 964 F.3d 141 (2d Cir. 2020) squarely addresses this question of standing. Although Defendants are correct that *Berni*, 964 F.3d at 147, applied the question of standing in the context of a motion for class certification, it nonetheless applied principles of Article III standing to determine whether non-plaintiff class members had standing to pursue injunctive relief. *See id*. at 147 n.25–27 (citing, *e.g.*, *Summers*, 555 U.S 488, 493 (2009), and *Lyons*, 461 U.S. at 111, to describe that "a threat of future injury must be 'actual and imminent, not conjectural or hypothetical.'"); *id*. at 148–49 (finding that "courts cannot permit injunctive relief through class settlement when plaintiffs

would otherwise lack standing to seek such relief under Article III"). The Circuit then concluded that "past purchasers of a product . . . are not likely to encounter future harm." *Id*. at 147. The Circuit did so because such purchasers are "not bound to purchase a product again—meaning that once they become aware they have been deceived, that will often the last time they will buy that item." *Id*. Such purchasers also "do not have the sort of perpetual relationship with the producer of a consumer good." *Id*. And even if they purchase it again, "there is no reason to believe that [they] . . . will incur harm anew. Supposing that they have been deceived by the product's packaging once, they will not again be under the illusion . . . ." *Id*. at 148. In a district court opinion issued one month before *Berni*, Judge Nathan issued a similar opinion, finding that the plaintiff did not have standing because the injury of that past purchaser was "*hypothetical—if* they choose to purchase Godiva's products in the future, *then* they *may* be harmed." *Hesse v. Godiva Chocolatier, Inc.*, 463 F. Supp. 3d 453, 465 (S.D.N.Y. 2020) (Nathan, J.) (emphasis in original);[8] *see also Campbell v. Whole Foods Mkt. Grp., Inc.*, 516 F. Supp. 3d 370, 395 (S.D.N.Y. 2021) (concluding that plaintiff's allegations that she "intends to, seeks to, and will purchase the Product again when she can do so with the assurance that Product's label is lawful and consistent with the Product's ingredients" is insufficient to confer standing to pursue injunctive relief (quoting the plaintiff's complaint)). Plaintiff does not explain why principles of Article III standing would differ in the class certification context for non-plaintiffs asserting

[8] As for Plaintiff's reliance on *Davidson v. Kimberly-Clark Corp.*, 889 F.3d 956 (9th Cir. 2018), this Court is not bound by out-of-circuit decisions, and at least in that case, the Ninth Circuit distinguished its decision from other Circuits by finding that the plaintiffs there had sufficiently alleged "their intention to repurchase the product at issue." *Id*. at 969 n.5. The plaintiff alleged that she "continues to desire to purchase wipes that are suitable for disposal in a household toilet," "regularly visits stores . . . where [Kimberly–Clark's] 'flushable' wipes are sold," and "is continually presented with Kimberly–Clark's flushable wipes packaging." *Id*. at 970. Plaintiff here has made no such allegations.

injunctive relief versus the named plaintiff seeking injunctive relief.

Plaintiff's reformulated theory of harm—that she "would purchase Non-Drowsy Equate Products again for non-drowsy use if they were actually 'Non-Drowsy' (*i.e.*, if the product was sold as advertised)" but that she "faces an imminent threat of harm because she will not be able to rely on the labels in the future, and thus will not be able to purchase the products," Dkt. No. 15 at 12—is insufficient to confer standing to pursue injunctive relief. Although Plaintiff attempts to distinguish this "particular theory of future harm," this theory suffers from the similar "conjectural" and "hypothetical" flaws. Namely, Plaintiff's injury from not being able to rely on the labels in the future, and thus not being able to purchase the products, only manifests if Plaintiff would have otherwise purchased the Product again, which remains entirely conjectural and hypothetical—as noted in *Berni*, there is no reason why Plaintiff would choose to buy the product again in the future. *Berni*, 964 F.3d at 147–48. She has not alleged any sort of "perpetual relationship" with Defendant that indicates that such injury of failed reliance would have arisen. *Id*. Further, Plaintiff's theory of harm is premised on the notion that she would not be able to rely on the labels in the future. But that injury is fundamentally premised on Plaintiff's *past* injury, and now knowing that the labels are unreliable, such labels are immaterial to her future decisions to purchase the product. For these reasons, Plaintiff does not have standing to assert injunctive relief.[9]

[9] The Court need not address Defendants' argument that Plaintiff lacks statutory standing to pursue non-New York consumer fraud claims because "[u]nlike Article III standing, which ordinarily should be determined before reaching the merits, statutory standing may be assumed for the purposes of deciding whether the plaintiff otherwise has a viable cause of action." *Coan v. Kaufman*, 457 F.3d 250, 256 (2d Cir. 2006) (citing *Steel Co. v. Citizens for a Better Env.*, 523 U.S. 83, 94–95 (1998)).

CONCLUSION

The motion to dismiss is GRANTED.

The Clerk of Court is respectfully directed to close Dkt. No. 22.

SO ORDERED.

Dated: October 28, 2022
New York, New York

LEWIS J. LIMAN
United States District Judge